K013891

FEB 0 5 2002

ATTACHMENT 6 - 510(k) Summary

1. **Applicant's Name and Address**

Straumann USA (on behalf of Institut Straumann AG)
Reservoir Place
1601 Trapelo Road
Waltham, MA 02451
Telephone Number: 781-890-0001
Fax Number: 781-890-6464
Contact Person: Linda Jalbert
Director, Regulatory Affairs

2. **Name of the Device**

Trade Name: ITI® synOcta Angled Abutments
Common Name: Dental implant abutment
Classification Name: Endosseous dental implants
21 CFR 872.3640

3. **Legally Marketed Devices to which Equivalence is Claimed (Predicate Devices)**

ITI synOcta Angled Abutment (K994119)

4. **Description of the Device**

The ITI Dental Implant System is an integrated system of endosseous dental implants which are designed to support prosthetic devices for partially or fully edentulous patients. The system consists of a variety of dental implants, abutments, and surgical and prosthetic parts and instruments. The devices covered by this submission are angled abutments which are placed into the dental implant to provide support for a prosthetic reconstruction. The angled abutment is used for angulation correction in cases where the position of the dental implant requires an angled reconstruction for an optimal restoration.

The 15° synOcta angled abutment for the Wide Neck Implant is made from commercially pure Grade 4 titanium (F67). The basal portion of the abutment has an 8° conical taper with an inset octagonal design. The abutment is seated in the implant with a screw, which is mounted in the

basal portion of the abutment. The abutment is used for cemented restorations.

5. **Intended Use of the Device**

The subject devices of this 510(k) are angled abutments which are used for angulation correction in cases where the position of the implant requires an angled abutment for optimal restoration. The subject abutments are designed for use with the ITI Wide Neck Implant with internal octagon. The subject abutments are modifications of the ITI synOcta angled abutments, cleared under K994119.

6. **Basis for Substantial Equivalence**

The ITI synOcta angled abutments for the Wide Neck Implant are substantially equivalent in intended use, material, and design to the ITI synOcta angled abutments cleared under K994119.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 5 2002

Institut Straumann AG
C/O Ms. Linda Jalbert
Straumann USA
1601 Trapelo Place
Waltham, Massachusetts 02451

Re: K013891
Trade/Device Name: SynOcta Angled Abutments for the ITI® Wide Neck Implant
Regulation Number: 872.3640
Regulation Name: Dental Implant Abutment
Regulatory Class: III
Product Code: DZE
Dated: January 28, 2002
Received: January 29, 2002

Dear Ms. Jalbert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613 . Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013891

Device Name: synOcta Angled Abutments for the ITI® Wide Neck Implant

Indications For Use:

The ITI synOcta angled abutments for Wide Neck Implants are indicated for use in cases where the placement of an implant requires an angled reconstruction for an optimal result. The abutment can be used to restore crowns for single tooth replacements and bridges for multiple tooth restorations.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use___ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013891